Remarks

Favorable consideration of this application is respectfully requested in view of the above amendments and the following remarks.

Claims 1, 3, and 6-18 are pending in the application. Claims 1 and 6-12 have been rejected. Claims 3 and 13-18 have been allowed. Claim 1 has been amended. Support for the amendments in claim 1 can be found throughout the specification and in claim 1 as originally filed. Claim 7 has been amended to merely correct a typographical error with respect to the proper dependency of claim 7. Claim 10 has been cancelled and new claims 19-21 have been added. Support for new claims 19 and 20 can be found in claims 1 and 10 as originally filed. Support for new claim 21 can be found on page 10 lines 6-13 and table 2 on pages 18 and 19 of the specification and in claims 1 and 8 as originally filed.

The Examiner also noted a typographical error in the specification on page 10, second paragraph, the word "by" should be written as "be". Applicants' amendment of the second paragraph on page 10 of the specification merely corrects a typographical error and does not add new matter.

At the outset, Applicants would like to acknowledge that claims 3 and 13-18 have been allowed and which allowance is appreciated. New claims 19 and 20 are dependent, either directly or indirectly, from claim 3, directed to the process for inhibiting and/or delaying carbamylation of a polypeptide in a urea and/or cyanate containing solution wherein the carbamylation-inhibiting compound is a dipeptide. Claims 19 and 20 further define the dipeptide as a Glycine-Glycine)Gly-Gly) or Glycine-Histidine (Gly-His). Applicants submit that these new claims are allowable for the same reasons that the process in claim 3 has been allowed.

I. The Rejection of Claims 1, and 6-12 Under 35 U.S.C. §103(a) May Properly Be Withdrawn

Claims 1 and 6-12 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication 2003/0045004 (Barri et al). According to the Examiner Barri et al teach the use of monomeric amino acids (e.g. listing by example

lysine, glycine, and arginine) and other enzymatic or non-enzymatic inhibitors of carbamylation, to inhibit or delay carbamylation of proteins in a urea or cyanate containing solution. Further, according to the Examiner Barri et al teach the use of any amino acid, which would include mono amino acids known to those of ordinary skill in the art, such as glycinamide, histidine, and 4-hydroxyl proline. Moreover, the Examiner asserts that if not inherently in the references, it would have been obvious to one of skill in the art at the time of the invention to arrive at a carbamylation percent protection of about 100% after three weeks, a compound concentration within the broad range of 1-150mM, and cyanate in the solution at a concentration of about 5mM, in the reference above, because the reference advantageously teaches the use of like compounds to carry out the decarbamylation of peptides (the underlying process), and arriving at the above ranges to carry out the same process is merely a matter of routine optimization by one of ordinary skill in the art, depending on the desired effect.

In response applicants have amended claim 1 to recite that the carbamylation-inhibiting compound is glycinamide. Applicants submit that in contrast to the Examiner's assertion glycinamide is not a monomeric amino acid but an amide. The carbamylation-inhibiting compound in claim 1, as amended, therefore is not a monomeric amino acid as is taught or suggested by Barri et al. Further, Applicants note, as well as the Examiner, that Barri et al with respect to their literature review state in paragraph [0009]: "Very few studies have been aimed at the prevention of carbamylation, and all have involved lens [eye] protein. [ ]. There are no studies in which any amino acid has been used to prevent carbamylation of proteins or lipids." Accordingly, Applicants submit that for the same reasons that using a dipeptide in the process of claim 3 is not taught or suggested by the prior art, the use of an amide, glycinamide, is likewise not taught or suggested by the cited reference because Barri et al, which the Examiner considers the closest prior art, is exclusively drawn to the use of mono amino acids with no teaching or suggestion to use an amide for the same purpose.

Therefore, the cited reference does not make obvious the presently claimed process for inhibiting and/or delaying carbamylation of a polypeptide in a urea and/or cyanate containing solution as defined in amended independent claim 1. In view of the

above, withdrawal of the rejection of claims 1 and 6-12 under 35 U.S.C. §103(a) is respectfully requested.

With respect to new claim 21, Applicants submit that the claimed process using histidine or 4-hydroxyl proline as the carbamylation-inhibiting compound is non-obvious in view of Barri et al. The cited reference fails to teach or suggest adding to a solution an effective amount to provide about 100% carbamylation protection of the polypeptide for a period of three weeks. Barri et al disclose the use of a mono amino acid in the treatment of an individual to reduce or prevent carbamylation. Barri et al only show in-vitro effectiveness in reducing carbamylation for a short period of time, for example over a period of 5 to 300 minutes (5 min to 5 hours) with lysine, arginine, or glycine. See Example 3, 11, and 16 in Barri et al. With respect to reducing or preventing carbamylation in an individual the reference fails to give any guidance as to the extent of the carbamylation reduction, let alone providing an effective amount for the reduction or protection of carbamylation at about 100% for three weeks. Moreover, because Barri et al is concerned with the reduction or prevention of carbamylation in individuals (in-vivo) there is no teaching or suggestion of administering an amount effective in providing a 100% protection for three weeks against carbamylation. Such effective amount may not be reasonably acceptable considering the in-vivo metabolism with respect to amino acids. To administer an effective amount to obtain about 100% protection for three weeks may require an undesirable dose.

Thus adding histidine or 4-hydroxyl proline to a solution in an effective amount to obtain about 100% protection against carbamylation for three weeks as in the presently claimed invention of claim 21 is not taught or suggested by Barri et al. Nor would one of ordinary skill in the art reading the disclosure of Barri et al be motivated to add an effective amount of histidine or 4-hydroxyl proline to a solution to provide about 100% protection against carbamylation for three weeks as discussed above. For these reasons, Applicants submit that new claim 21 is allowable in view of the cited art.

A good faith effort has been made to place the present application in condition for allowance. If the Examiner believes a telephone conference would be of value, he is requested to call the undersigned at the number listed below.

Dated: July 3, 2007

Respectfully submitted,

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